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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,507	07/15/1998	VINCENT G. H. EIJSINK	1380-122PCT	2387

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/068,507

Applicant(s)

EIJSINK ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003 & 30 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 107, 109-111 and 126-134 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 107, 109-111, 126-134 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2003 has been entered.

The AF amendment filed September 10, 2003 canceling claims 1-106, 108 and 112-125, amending claims 107 and 109 and adding claims 126-134 has been entered.

The Sequence Listing and the computer readable form thereof filed September 10, 2003 have been entered.

Claims 107, 109-111 and 126-134 are pending.

### ***Claim Objections***

Claims 107, 109-111 and 126-134 are objected to because of the following informalities: the claims recite "residues" of a nucleotide sequence. It is customary to use the term "nucleotides" in relation to a nucleotide sequence.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 107 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 107 is drawn to a nucleic acid comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10. Thus, claim 107 encompasses a genus of nucleic acids of any structure and length defined by about 17 nucleotides having any function. Said genus encompasses naturally occurring and man made sequences.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species

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means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case, the genus is highly variant because a significant number of structural and functional differences between genus members is permitted. No common function identify the members of the genus. The specification teaches the structure of naturally occurring sequences comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10. Said nucleotide sequences are sequences of inducible promoters. However, the claimed genus is not limited by function and encompasses sequence with potentially different functions. Moreover, the specification fails to describe correlation between structure and function common to all members of the genus.

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Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 107, 109-111 and 126-134 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10 inducible by a peptide defined by the amino acid sequence consisting of SEQ ID NO: 1 or residues 19-37 of SEQ ID NO:3, does not reasonably provide enablement for a promoter comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10 inducible by any compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claims encompass engineered promoters induced by any compound of unknown structure.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the large number of nucleotides sequences broadly encompassed by the claims. The specification does not provide a guidance with regard to the rest of the structure and its effect on the promoter's function.

The specification does not support the broad scope of the claims which encompass promoters inducible by any compound because the specification does **not** establish a rational and predictable scheme for modifying nucleotides with an expectation of obtaining the desired biological function and the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Further, without knowing the inducer, one of ordinary skill in the art would not know how to use a promoter inducible by unknown compound in addition to not knowing how to make it.

Thus, applicants have **not** provided sufficient guidance to enable one of ordinary skill in the art to make and/or the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid of any function comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38

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of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10 or a promoter comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10 inducible by an inducer other than SEQ ID NO:1 or residues 19-037 of SEQ ID NO:3. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of a promoter inducible by an unknown compound is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 107 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether claim 107 is drawn to a naturally occurring sequence comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6, nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10 that is a promoter or to any sequence comprising nucleotides 7-14 and 30-38 of SEQ ID NO:6,



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nucleotides 7-14 and 30-38 of SEQ ID NO:7, nucleotides 7-14 and 30-38 of SEQ ID NO:8, nucleotides 7-14 and 31-38 of SEQ ID NO:9 or nucleotides 7-8, 10-14 and 31-38 of SEQ ID NO:10 having any function.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 107 is rejected under 35 U.S.C. 102(b) as being anticipated by Tichaczek et al.

Tichaczek et al.(form PTO-1449 filed August 11, 1998) disclose the sakacin P gene cluster. Said nucleic acid comprises SEQ ID NOs: 6-8 and therefore, the fragments thereof recited in claim 107.

Claim 107 is rejected under 35 U.S.C. 102(b) as being anticipated by Tichaczek et al.

Diep et al. (1994, form PTO-1449 filed August 11, 1998) disclose the plantaricin A gene cluster.

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Said nucleic acid comprises SEQ ID NO: 10 and therefore, the fragments thereof recited in claim 107.

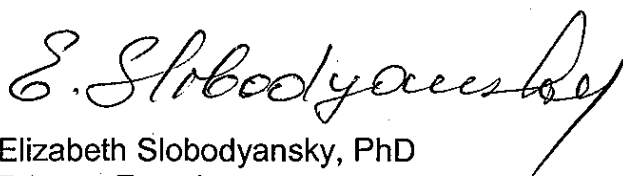
***Response to Arguments***

Applicant's arguments filed September 10, 2003 have been fully considered but they are not persuasive. These arguments as they apply to the currently pending claims have been addressed in the Advisory action mailed October 9, 2003. The majority of arguments are moot as they are related to the rejections not currently at issue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD  
Primary Examiner